

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q94121

Masao SUDOH, et al.

Appln. No.: 10/574,477

Group Art Unit: 1621

Confirmation No.: 2361

Examiner: Sadhakar KATAKAM

Filed: January 9, 2007

For: DRUG CONTAINING (2R)-2-PROPYLOCTANOIC ACID AS THE ACTIVE
INGREDIENT

REQUEST FOR REFUND

MAIL STOP 16

Director of the U.S. Patent and Trademark Office

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

Applicant received a Non-Final Office Action from the United States Patent and Trademark Office dated May 23, 2007, in which the Office Action Summary indicated that the period for reply was set for three (3) months. The Office Action Summary also indicated that claims 1-34 are pending in the application and claims 1-31, 33-34 are subject to restriction and/or election requirement. Applicant electronically filed a Response to Restriction and Election of Species Requirement in the USPTO on August 22, 2007 and was charged \$450.00 for a two-month Extension of Time. Applicant believes the charged is incorrect since the Office Action Summary indicated a three (3) month period to reply and the Response was timely filed.

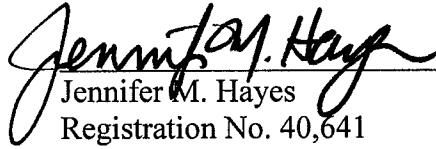
Applicant hereby respectfully requests a refund in the amount of \$450.00. This refund is to be credited to Deposit Account No. 19-4880.

REQUEST FOR REFUND
U.S. Appln. No.: 10/574,477

Attorney Docket No.: Q94121

A copy of the Deposit Account Monthly Statement showing the charge to our account,
and a copy of Office Action dated May 23, 2007 are enclosed.

Respectfully submitted,


Jennifer M. Hayes
Registration No. 40,641

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DATE POSTED			CONTROL NO.	DESCRIPTION (Serial, Patent, TM, Order)	DOCKET NO.	FEE CODE	CHARGES/ CREDITS	BALANCE
MO.	DAY	YR.						
9	4	07	93	11817567	Q103532	8021	40.00	173975.48
9	4	07	111	11848639	Q101179	1011	300.00	173675.48
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9	4	07	1378	11848723	Q103538	8021	40.00	163515.48
9	4	07	1440	11848748	Q102069	8021	40.00	163475.48
9	4	07	1502	11817610	Q103655	1631	300.00	163175.48
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9	4	07	1504	11817610	Q103655	1633	200.00	162575.48
AN AMOUNT SUFFICIENT TO COVER ALL SERVICES REQUESTED MUST ALWAYS BE ON DEPOSIT					OPENING BALANCE	TOTAL CHARGES	TOTAL CREDITS	CLOSING BALANCE



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,477	01/09/2007	Masao Sudoh	Q94121	2361

23373 7590 05/23/2007
SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

DOCKETED

MAY 24 2007

EXAMINER

KATAKAM, SUDHAKAR

ART UNIT	PAPER NUMBER
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1621

MAIL DATE	DELIVERY MODE
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05/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/574,477

Applicant(s)

SUDOH ET AL.

Examiner

Sudhakar Katakam

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-31, 33-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-17, 20-28, 33-34, drawn to a medicament comprising (2R)-2-propyloctanoic acid and a basic metal ion.

Group II, claim 18, drawn to a method of making a medicament comprising (2R)-2-propyloctanoic acid.

Group III, claim 19, drawn to a method of using a basic metal ion, which comprises (2R)-2-propyloctanoic acid.

Group IV, claim(s) 29-30, drawn to a container made of plastics, which is filled with (2R)-2-propyloctanoic acid, disodium hydrogen phosphate dodecahydrate and sodium hydroxide.

Group V, claim 31, drawn to a method of preventing and/or treating neurodegenerative diseases, nerve disorder or diseases in need of nerve regeneration, which comprise administering an effective amount of medicament comprising (2R)-2-propyloctanoic acid or a salt thereof and a basic metal ion.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature in all groups is the "2-propyloctanoic acid". This element is shown in the prior art (US 6,201,021) teaches the same ester system. Thus, there is no special technical feature connecting all the claims.

Because these inventions are independent or distinct for the reason given above and there would be a serious burden on the examiner if restriction were not required; because the inventions require a different field of search (see MPEP § 808.02) restriction for examination purposes as indicated is proper.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

3. A telephone call was not made because of the complex nature of claims.
4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Upon election of invention of groups I-V, applicant needs to elect a single disclosed species for examination purposes for either of the group elected. Claims will be examined to the extent they read on the elected species and closely related compounds. Applicant should identify all the claims that are readable on elected species.

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

See claims and the examples disclosed in the specification.

Applicant must identify exact and full name of a species for the account of examination purpose and identify the claims readable upon.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. The following claims are generic:

Claims 1-6 and 11-30 are generic.

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the special technical feature which is referred to Annex B of Appendix A1 of MPEP (Administrative

Art Unit: 1621

Instructions under the PCT, "Unity of Invention"). Unity exists only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding claimed technical features. The express "special technical features" is defined as meaning those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art ("Rule 13.2). The question of unity of invention has been reconsidered retroactively by the examiner in view of the search performed; a review of prior art (US 6,201,021) makes clear that the claimed "2-propyloctanic acid" is not novel over the prior art. Furthermore, these reference appear to demonstrate that the claimed "2-propyloctanic acid" analog does not define a contribution which each of the inventions, considered as a whole, makes over the prior art. Accordingly, the prior art of the record supports restriction of the claimed subject matter in to the groups as mentioned above.

8. A telephone call was not made because of the complex nature of claims.
9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of

record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richer can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SK


SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1200

Notice of References Cited	Application/Control No. 10/574,477	Applicant(s)/Patent Under Reexamination SUDOH ET AL.	
	Examiner Sudhakar Katakam	Art Unit 1621	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-6,201,021	03-2001	Ohuchida et al.	514/558
	B	US-			
	C	US-			
	D	US-			
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
	L	US-			
	M	US-			

FOREIGN PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Country	Name	Classification
	N					
	O					
	P					
	Q					
	R					
	S					
	T					

NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	
	V	
	W	
	X	

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.